The paragraph beginning on page 1, line 1 is amended as follows:

Bandages and wound dressings are simple, familiar devices that everyone uses.

At least they used to be simple. In an effort to hasten the wound healing process or and reduce the risk of infection, there have been many recent efforts to redesign, or sometimes redefine, a bandage. Unfortunately, very few Few people have enjoyed the benefits of some new bandages, a "super bandage" because they are either too complex or too expensive to be widely used, let alone reach the medicine cabinets of the general public. The present invention is a method of making an improved sterile bandage that is superior to traditional bandages, but retains the simple and familiar aspects that are expected of a bandage.

The paragraph beginning on page 1, line 16 is amended as follows:

wound is easy, and there are numerous products that fill that need. Delivering silver to a wound, however, has posed many difficulties because silver is a metal. How do you apply a dosage of metal into a wound? Granted, powdered silver could be sprinkled over a wound from a pepper shaker in the hope that the body will only absorb as much silver as is needed, but excess absorption of silver will turn skin bluish gray (although there are no known health dangers). Not surprisingly, most of the prior art does Some methods resort to using silver crystals, which have a large relative surface area, and the primary goal seems to be to deliver as much silver as possible into the wound. Colloidal silver, silver salts (e.g. silver nitrate) and silver compounds (e.g. silver sulfadiazine) have been used to make creams and

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ointments, which. Creams and ointments are have always been popular in the field of medicine because they are easy to use and familiar.

### The following paragraph beginning on page 2, line 8 is amended as follows:

There are numerous devices that rely on either an external electrical power source or a direct reaction between silver and another material metal to generate the production of silver ions. ACTISORB<sup>TM</sup> consists of activated carbon impregnated with metallic silver.

ACTICOAT 7<sup>TM</sup>, developed by Dr. Robert Burrell, uses a vapor deposition technique to apply a coating of a binary alloy of silver and oxygen onto a mesh. Dr. Robert O. Becker used electricity (often from a coin battery) to produce free silver ions that penetrate into the wound tissue. Dr. William E. Crisp, et al., took the approach of amalgamating metals within a thickness of material, such as a sponge, to create a direct reaction that releases silver into a wound. Unfortunately, these prior art devices may require expensive manufacturing processes, and the devices themselves can be complex and cumbersome.

### The following paragraph beginning on page 2, line 20 is amended as follows:

In an embodiment, an article includes a primary surface, and a pattern of spaced dissimilar materials, on the primary surface. The pattern is to spontaneously produce electrical surface currents when brought into contact with an electrically conducting solution. The present invention is an inexpensive method of making a pattern of spaced dissimilar conductors on a surface, visible with the naked eye, that will spontaneously produce an electrical current when brought into contact with an electrolytic solution. In the most preferred embodiment, numerous silver and zine conductors are painted or printed in spaced relation to one another on a biocompatible surface, such as the primary surface of a traditional bandage. High purity silver is mixed with a biocompatible binder, such as a polyacrylic ink, to form a thick liquid "silver ink",

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and high purity zinc is mixed with a biocompatible binder to form "zinc ink". The silver ink and the zinc ink can be applied to a suitable surface using a readily available screen printing apparatus, such as those used to print T-shirts. The desired conductor pattern can be printed directly onto a surface, and then cured so that the conductors are fixed in a predetermined pattern or array. Once the pattern of conductors is brought into contact with an electrolytic solution, such as wound fluid, numerous voltaic cells start generating electrical currents. Incidental to these spontaneous electrochemical reactions, silver and zinc are released into the wound.

### The following paragraph beginning on page 3, line 16 is amended as follows:

Fig. 2 is a detailed plan view of the preferred a pattern of printed electrical conductors in accordance with an embodiment of the present invention.

### The following paragraph beginning on page 4, line 20 is amended as follows:

The detailed description of <u>embodiments of</u> the present invention has been broken into two sections. The first section will teach how to make the preferred and alternate embodiments. The second section explores the theories that <u>may</u> explain why <u>embodiments of</u> the present invention <u>achieve beneficial results</u> works, but it is not necessary to understand these theories in order to make, use or otherwise benefit from <u>embodiments of</u> the present invention. The complexities of the human body, combined with our limited understand of the healing process, requires the realization that these theories will improve over time. Any inaccuracies or oversimplifications of the theories presented in the second section should in no way detract from the scope of the claims, which focus on the <u>embodiments</u> articles of manufacture and not the theories.

The A preferred embodiment is includes a bandage, more generally a wound dressing, but the a method for making a wound dressing, in accordance with an embodiment of the present invention, can similarly be applied to virtually any medical device that contacts an electrolyte of the body, as will be apparent to one of skill in the art, based on the description herein. Actually, embodiments of the present invention can be applied to virtually any non-conductive surface that may come into contact with an electrolytic solution.

The A purpose of using the present invention is primarily to reduce infection and contamination, but there are additional benefits specific to wound care that are of exceptional value. These benefits will be addressed in the second section.

The following paragraph beginning on page 6, line 6 is amended as follows:

Ironically, the most preferred dissimilar Dissimilar metals used to make the preferred embodiment of the present invention (a wound dressing) are silver and zinc, and the electrolytic solution is predominantly includes sodium chloride in water. The A unique aspect of some embodiments of the present invention is that the electrodes are painted or printed onto a non-conductive surface to create a pattern, most preferably an array, of voltaic cells that do not spontaneously react until they contact an electrolytic solution, such as wound fluid. The remainder of this description will use the terms "printing" with "ink", but it is understood that the embodiments may instead be "painted" with "paints". It is also assumed that a competent printer will know how to properly apply and cure the inks without any

assistance, other than perhaps instructions that should be included with the selected binder that is used to make the ink mixtures that will be used in the printing process.

# The following paragraph beginning on page 6, line 17 is amended as follows:

In Fig. 1, the electrodes are printed onto a desired primary surface 2 of an article 4 which, in the preferred embodiment, is that surface of a wound dressing that comes into direct contact with a wound. In alternate uses embodiments of the present invention, the primary surface is one which simply should needs to be antimicrobial, such as a medical instrument, implant, surgical gown, gloves, socks, table, door knob, or other surface that will contact an electrolytic solution, including sweat, so that at least part of the pattern of voltaic cells will spontaneously react and kill bacteria or other microbes.

#### The following paragraph beginning on page 7, line 3 is amended as follows:

The printed electrodes adhere or bond to the primary surface 2 because a biocompatible binder is mixed, into separate mixtures, with each of the dissimilar metals that will create the pattern of voltaic cells, in an embodiments. Most inks are simply a binder mixed with pigment. Similarly, the metal inks are a binder mixed with a conductive element. The resulting metal ink mixtures may be are used with an a common application method, such as screen printing, in an embodiment, to apply the electrodes to the primary surface in predetermined patterns. Once the inks dry and/or cure, the patterns of spaced electrodes will substantially maintain their relative position, even on a flexible material such as cloth. To make only a few of the wound dressings of an embodiment of the present invention, the mixtures can be hand painted onto a common adhesive bandage so that there is an array of

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alternating electrodes that are spaced about a millimeter apart on the primary surface of the bandage. The paint should be allowed to dry before being applied to a wound so that the zinc ink does not mix with the silver ink, which would destroy the array and cause direct reactions that will release the elements, but fail to simulate the current of injury, as will be explained later.

# The following paragraph beginning on page 7, line 17 is amended as follows:

The binder is may include any biocompatible liquid material that can be mixed with a conductive element (preferably metallic crystals of silver or zinc) to create an ink which may be applied as a thin coating to a surface. One suitable binder is a solvent reducible polymer, such as the polyacrylic non-toxic silk-screen ink manufactured by Colorcon, Inc., a division of Berwind Pharmaceutical Services, Inc. (see Colorcon's No-Tox® product line, part number NT28). The binder is mixed with high purity (at least 99.999%, in an embodiment is recommended) metallic silver crystals to make the silver ink, in an embodiment. The silver crystals, which are made by grinding silver into a powder, are preferably smaller than 100 microns in size, or about as fine as flour. The preferred In an embodiment, the size of the crystals is about 325 mesh, which is typically about 40 microns in size, or a little smaller. The binder is separately mixed with high purity (at least 99.99%, in an embodiment is recommended) metallic zinc powder, in an embodiment, which has also preferably been sifted through standard 325 mesh screen, to make the zinc ink. For better quality control and more consistent results, most of the crystals used should be larger than 325 mesh and smaller than 200 mesh. Other powders of metal can be used to make other metallic inks in the same way as just described, in other embodiments.

In various embodiments, when When a single mass of silver ink is spaced from a single mass of zinc ink, a single voltaic cell is created if when an electrolytic solution electrically connects the masses. If a single mass of silver ink is spaced from two masses of zinc ink, then two voltaic cells are created, and so on. To maximize the number of voltaic cells, in various embodiments, a pattern of alternating silver ink masses and zinc ink masses may will create an array of electrical currents across the primary surface. A very basic pattern, shown in Fig. 1, has each mass of silver ink equally spaced from four masses of zinc ink, and has each mass of zinc ink equally spaced from four masses of silver ink, according to an embodiment. The first design 6 is separated from the second design 10 by a spacing 8. The designs, which are simply round dots, in an embodiment, are repeated. Numerous repetitions 12 of the designs result in a pattern. For a wound dressing, each silver ink design preferably has about twice as much mass as each zinc ink design, in an embodiment. For the pattern in Fig. 1, the silver ink designs are most preferably about a millimeter from each of the closest four zinc ink designs, and visa-versa. The resulting pattern of dissimilar metal masses defines an array of voltaic cells when introduced to an electrolytic solution.

## The following paragraph beginning on page 11, line 9 is amended as follows:

There are numerous possible creative choices of patterns, but some patterns will work better with certain combinations of inks. Because the spontaneous oxidation-reduction reaction of silver and zinc <u>uses approximately requires</u> two silver and one zinc, the silver ink design should <u>may</u> contain about twice as much mass as the zinc ink design, in an

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embodiment. At a spacing of about 1 mm between the closest dissimilar metals (closest edge to closest edge), each voltaic cell that is in wound fluid will may create approximately 1 volt of potential that will penetrate substantially through the dermis and epidermis. Closer spacing of the dots may will decrease the resistance, provide less potential, and the current will not penetrate as deeply. If the spacing falls below about one tenth of a millimeter, the only a realized benefit of the spontaneous reaction is that which is also present with a direct reaction-silver is electrically driven into the wound, but the current of injury is may not be substantially simulated.

The following paragraph beginning on page 12, line 11 is amended as follows:

Although it It has proven to be beneficial to drive silver into the wound. In addition, in accordance with embodiments of, that is not of primary importance in the present invention, because the induced electrical current has been shown to electrochemically attract microbes to the surface of the bandage, so that many of the killed microbes are removed with the bandage instead of accumulating within the wound and necessitating the phagocytic engulfment and removal by macrophages in the natural but slower process of wound healing. Of additional concern in not removing dead bacterial cells from the wound vicinity is the release of toxic enzymes and chemicals from the dead and degrading bacteria, thought to be alleviated by application of embodiments of the present invention. Bacteria and other microbes are specifically drawn to the cathode (silver in the preferred embodiment) by virtue of their overall net negative charge along the created electric gradient. Because all microbes are net negatively charged, they die when they contact silver.

The following paragraph beginning on page 13, line 1 is amended as follows:

The most preferred material to use in combination with silver to create the voltaic cells of embodiments of the present invention is zinc. Zinc, which has been well-described for its uses in prevention of infection in such topical antibacterial agents as Bacitracin zinc, a zinc salt of Bacitracin. Zinc is a divalent cation with antibacterial properties of its own in addition to possessing the added benefit of being a cofactor to proteins of the metalloproteinase family of enzymes important to the phagocytic debridement and remodeling phases of wound healing. As a cofactor, zinc promotes and accelerates the functional activity of these enzymes, resulting in better, more efficient wound healing.

The following paragraph beginning on page 13, line 16 is amended as follows:

The voltage present needed at the sight of a wound has been traditionally in the range of millivolts, but embodiments of the present invention may introduce introduces a much higher voltage, near 1 volt when using the 1 mm spacing of dissimilar metals already described. The higher voltage is believed to drive the current deeper into the wound bed so that dermis and epidermis benefit from the simulated current of injury. In this way, the current not only drives some silver and zinc into the wound to kill microbes, but the current also provides the necessary stimulatory current of injury so that the entire wound surface area can heal simultaneously, in an embodiment. Without the wound dressing of embodiments of the present invention, the current of injury may only naturally exist exists at the periphery of the wound that is within about half a millimeter of undamaged skin. That is why a wound

closes from the edges in. The obvious  $\underline{A}$  benefit of covering the entire wound with a simulated current of injury, in accordance with various embodiments, is that the volume of skin being repaired at the same time is may be significantly increased.

The following paragraph beginning on page 14, line 15 is amended as follows:

Finally, it is important preferable to control the release rate of the dissimilar metals of the current producing wound dressing of various embodiments for two reasons, each in opposition to the other. In the preferred embodiment, the voltaic cells of the wound dressing drive the simulated current of injury deeper into the wound area if the dissimilar metals are kept separated by a predetermined distance, such that it would be undesirable to allow the silver to freely mix into the wound fluids as this would quickly result in a quenching of the electrochemical gradient and thus an extinguishing of the desired voltaic effect. On the other hand, if a predetermined quantity of silver is allowed to mix into the wound, the silver will help prevent wound infection. (Please note that the spontaneous reactions of the voltaic cells will release elements into the wound even though the most desired method of killing microbes is at the cathodes, as already described.)

The following paragraph beginning on page 15, line 4 is amended as follows:

Because it is desirable to have both the current of injury and the antimicrobial effects of silver present, a compromise may must be made. To achieve a this optimal balance, the binder should release silver and zinc into the wound while simultaneously maintaining the simulated current of injury for the entire period of time that the bandage is

intended to be left on the wound. Wound dressings that should be changed more often can have a shorter life as a current producing dressing, so the release rate of the binder can be faster. Wound dressings that are intended to be left on the wound for an extended period of time, say 10 days, should have a binder that does not dissolve or otherwise breakdown as quickly, or the percentage of binder to metallic crystals should be higher. This can be controlled by the intelligent selection of different mixture ratios and/or binder materials having longer or shorter half-lives or absorption rates, in various embodiments.

The following paragraph beginning on page 15, line 15 is amended as follows:

While a preferred form various embodiments of the invention have has been shown and described, it will be realized that alterations and modifications may be made thereto without departing from the scope of the following claims. For example, it may be desirable to use methods other than difficult, or impossible, to use a common screen printing machine to print the electrodes of the present invention onto surfaces on medical instruments, garments, implants and the like so that they are antimicrobial. It is expected that a known method other methods of applying the paint or ink may will be substituted as appropriate.

Also, there are numerous shapes, sizes and patterns of voltaic cells that have not been described, but it is expected that this teaching will enable those skilled in the art to incorporate their own designs which will then be painted or printed onto a surface to create voltaic cells which will become active when brought into contact with an electrolytic solution.